K010694

FEB 1 1 2002

510(k) Summary

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

This summary of 510(k) safety and effectiveness is being submitted in accordance with 21 CFR 807.92.

Novare Surgical Inc. intends to introduce into commercial distribution the iNcluder™ vascular clamp. The equivalent predicate devices are the Baladi Inverter vascular clamp (#K980128) by Cardio Medical Solutions Inc. and the Fogarty Hydragrip vascular clamp (a Pre amendments device) by Allegiance Healthcare Corporation.

The FDA has classified devices of this type – vascular clamps, as Class 2 devices per 21 CFR 870-4450. Novare Surgical's iNcluder™ vascular clamp is a Class 2 medical device. The common name for Novare's device is vascular clamp.

The iNcluder™ vascular clamp is intended for use by cardiac surgeons during coronary artery bypass grafting (CABG) procedures to create hemostasis and to facilitate the proximal anastomosis. The Baladi Inverter, Fogarty Hydragrip and Novare's vascular clamps are all used by cardiac surgeons to create temporary hemostasis during bypass grafting. In all three devices, hemostasis is obtained by temporarily sealing a small region of the inside wall of the aorta. The device labeling supports the use of these devices in the discipline of cardiac surgery.

Russell J. Anderson 1/24/02

Russell J. Anderson date
Engineering Director
Novare Surgical Systems Inc.
10231 Bubb Rd.
Cupertino, CA 95014

Phone (408) 350-9931

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Mr. Russel J. Anderson
Engineering Director
Novare Surgical Systems, Inc.
10231 Bubb Road
Cupertino, CA 95014

Re: K010694
Trade Name: iNcluder™ Vascular Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name:
Regulatory Class: Class II (two)
Product Code: DXC
Dated: January 24, 2002
Received: January 26, 2002

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

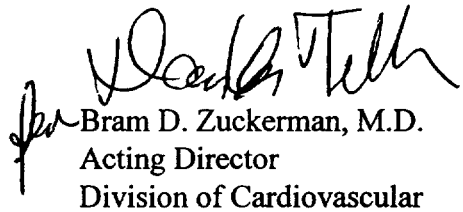
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) #k010694 Submission Supplement (1/24/02)

INDICATIONS FOR USE SHEET

Indications For Use – The Includer Clamp is intended for use by cardiac surgeons in place of partial occluding clamps during coronary artery bypass grafting (CABG) procedures requiring a single proximal anastomosis in ascending aortas free of atheromatous disease.

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010694